



October 24, 2018

Cordis Corp.  
Karen Wilk  
Manager, Regulatory Affairs  
7 Powder Horn Dr.  
Warren, New Jersey 07059

Re: K020316

Trade/Device Name: Cordis TRAPEASE™ Permanent Vena Cava Filter with the VISEASE™  
Angiographic Vessel Dilator

Regulation Number: 21 CFR 870.3375

Regulation Name: Cardiovascular intravascular filter

Regulatory Class: Class II

Product Code: DTK, DRE, DQO

Dated: January 29, 2002

Received: January 30, 2002

Dear Karen Wilk:

This letter corrects our substantially equivalent letter of March 20, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Kenneth J. Cavanaugh -S**

for

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

510(k) Number:

K020316

Device Name:

Cordis TRAPEASE™ Permanent Vena Cava Filter with the  
VISEASE™ Angiographic Vessel Dilator

Indications for Use:

The Cordis TrapEase™ Permanent Vena Cava Filter is indicated for the prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava in the following situations: pulmonary thromboembolism when anticoagulants are contraindicated, failure of anticoagulant therapy in thromboembolic diseases, emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced and chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The VisEase Angiographic Vessel Dilator is designed to provide angiographic visualization and linear measurement of the vasculature when combined with the delivery of radiopaque contrast media to the vena cava.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒


OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K020316

MAR 20 2002

510(k)  
Summary of Safety and Effectiveness

K020316

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**Date Prepared:** January 29, 2002

**General Provisions:** Trade Name: Cordis TrapEase™ Permanent Vena Cava Filter with the  
VisEase™ Angiographic Vessel Dilator

Common Name: Permanent Vena Cava Filter and Introduction Kit

Classification Name: Cardiovascular Intravascular Filter (per 21 CFR 870.3375)

Device Classification: Class II

**Predicate Devices:** The subject TrapEase Permanent Vena Cava Filter with the VisEase Angiographic Vessel Dilator is substantially equivalent to:

- Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit (510(k) #K000062, #K003964 and #K010083)
- Cordis 5F Super Torque MB Angiographic Catheter (510(k) #K992347).
- Cordis 5.2 F Super Torque Plus Angiographic Catheter (510(k) #K914007)
- Cordis Brite Tip Catheter Sheath Introducer & Vessel Dilator (510(k) #K983023 and #K984500)

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**Performance Standards**

As per 21 CFR 870.3375, the following special controls were established for cardiovascular intravascular filters:

- Use of International Standards Organization's ISO-10993 'Biological Evaluation of Medical Devices Part I: Evaluation and Testing,
- FDA's 510(k) Sterility Review Guidance and Revision of November 16, 2001 (K90-1), and
- FDA's Guidance for Cardiovascular Intravascular Filter 510(k) Submissions

For the Angiographic Catheter and vessel Dilator performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

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**Indications for Use**

[Unchanged from the predicate devices:] The Cordis TrapEase™ Permanent Vena Cava Filter is indicated for the prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated,
- failure of anticoagulant therapy in thromboembolic diseases,
- emergency treatment following massive pulmonary embolism, where anticipated benefits of conventional therapy are reduced and
- chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

[New:] The VisEase Angiographic Vessel Dilator is designed to provide angiographic visualization and linear measurement of the vasculature when combined with the delivery of radiopaque contrast media to the vena cava.

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**Device Description**

The subject TrapEase Permanent Vena Cava Filter with the VisEase Angiographic Vessel Dilator most notably differs from the predicate TrapEase Permanent Vena Cava Filter and Introduction Kit with regards to the vessel dilator that is included as a component in the Introduction Kit. In addition to its original function as a vessel dilator, which was featured with the predicate Cordis TrapEase Introduction Kits, the subject VisEase Angiographic Vessel Dilator features new intended uses involving angiographic visualization and linear measurement. These new intended uses of the subject VisEase Angiographic Vessel Dilator are addressed in updated product labeling herein and are identical to the intended uses of the predicate Cordis Super Torque MB Angiographic Catheter (reference K992347, determined substantially equivalent on October 8, 1999).

Besides the aforementioned changes in intended use for the VisEase Angiographic Vessel Dilator, the TrapEase Permanent Vena Cava Filter and all other components used with the subject device remain unchanged from that featured with the predicate devices (reference 510(k) Notifications #K000062, #K003964 and #K010083).

**Performance Data:** The safety and effectiveness of the Cordis TrapEase Permanent Vena Cava Filter and VisEase Angiographic Vessel Dilator have been demonstrated via data collected from non-clinical design verification tests and analyses. The design verification testing consisted of the following:

- Visual and Dimensional Inspection
- Catheter Sheath Introducer Compatibility
- Flow Rate Testing
- Hydrodynamic Testing
- Pull Strength Testing

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**Summary of Substantial Equivalence** The design, material, components, fundamental technology and intended use featured with the Cordis TrapEase Permanent Vena Cava are substantially equivalent to those featured with the predecessor Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit (reference 510(k) #K000062, #K003964 and #K010083). The design, material and new intended uses of the VisEase Angiographic Vessel Dilator are substantially equivalent to those featured with the predicate Cordis Super Torque MB Angiographic Catheter (reference 510(k) #K992347) and Cordis 5.2 F Super Torque Plus Angiographic Catheter (510(k) #K914007).